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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/055,744	04/07/1998	CHARLES D. Y. SIA	1038-746-MIS	4350

7590 12/19/2001

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EXAMINER

BUDENS, ROBERT D

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 12/19/2001

22

Please find below and/or attached an Office communication concerning this application or proceeding.

09/055,744



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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 10/10/01

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1, 4-15 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☒ Claim(s) 12 is/are allowed.
☒ Claim(s) 1, 4-11 is/are rejected.
☒ Claim(s) 13-15 is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☒ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

—SEE OFFICE ACTION ON THE FOLLOWING PAGES—

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The Examiner acknowledges Applicant's Amendment, Paper No. 21, filed October 10, 2001. In view of Applicant's Amendment, the status of the claims is as follows: Claims 2-3 have been canceled; Claims 1 and 4-15 are currently pending before the Examiner.

The rejection of claim 3 and 6-15 under 35 U.S.C. § 112, second paragraph, is withdrawn in view of Applicant's amendment.

Claims 13-15 are objected to under 37 C.F.R. 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Applicant has amended independent claim 12 to recite language "A peptide consisting of..." which is closed claim language limiting the structure of the claimed invention. Dependent claims 13-14 add limitations which exceed the scope of the closed claim language of claim 12 and are, therefore, in improper form.

Claims 1 and 4-11 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons of record set forth in the last Office Action. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection. Applicant argues that the claimed invention "do not promise that the procedure of the invention is a vaccination procedure against HIV and neither does applicants data demonstrate the same" (see Paper No. 21, paragraph bridging pages 3-4). This is not persuasive.

While the Examiner agrees that Applicant's data do not support claims for a vaccine method since there is no convincing evidence of record to establish that the methods of the claimed invention would result in a protective immune response against HIV, this is not the only issue with respect to Applicant's claimed invention. Applicant is broadly claiming "A method of generating an HIV-specific cytotoxic T-cell (CTL) response in a host..." (see Claim 1, and Paper No. 21, paragraph bridging pages 3-4). The scope of Applicant's invention encompasses the generation of CTLs in any host. However, as set forth in the last Office Action, Applicant's data is only directed to methods using MHC Class I HLA A2 molecules. Applicant admits on the record that the present invention is based on a few limited oligopeptides, CLP-177, CLP-72, CLP-178 and CLP-182, as well as a long peptide (SEQ ID NO: 9) which were capable of binding to an HLA class I molecule, A2 (see Paper No. 15, paragraph bridging pages 3-4). There are no teachings in the specification of other peptides which could bind with HLA A2 and stimulate an anti-HIV cell-mediated immune response nor is there any evidence of other peptides which could bind to other HLA class I molecules.

As evidenced by the teachings of Falk et al. and Deng et al. (see Applicant's Information Disclosure Statement, Paper No. 17, items 2 and 6), there are numerous HLA class I molecules each having its own particular consensus motif for binding oligopeptides (see Falk et al., Abstract). Further, as evidenced by Deng et al., even peptides that do bind to a particular HLA class I molecule, do not necessarily elicit satisfactory immune responses. Deng et al. discovered that while they could identify ten peptides which would bind to MHC K^d (a mouse class I histocompatibility molecule analogous to the HLA class I molecules in humans), only five of the peptides elicited a secondary CD8+ response (see Abstract). Thus, the evidence of Falk et al. and Deng et al. establish the unpredictable nature of identifying oligopeptides suitable for binding to HLA class I molecules and capable of eliciting immune

responses. Applicant has not set forth any convincing arguments or evidence to rebut this rejection. In the absence of convincing objective evidence, the rejection is deemed proper and is maintained.

5 Claim 12 is allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

10 A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37
15 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

20 Papers relating to this application may be submitted to Group 1600 by facsimile transmission. The Fax number is (703) 308-4242. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

25 Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Robert D. Budens at (703) 308-2960. The Examiner can normally be reached Monday-Thursday from 6:30 AM-4:00 PM, (EST). The Examiner can also be reached on alternate Fridays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James
30 Housel, can be reached at (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at

Serial No. 09/055,744
Art Unit 1648

(703) 308-0196.

A handwritten signature in black ink, appearing to read "Robert D. Budens". The signature is fluid and cursive, with the first name "Robert" and last name "Budens" clearly distinguishable.

Robert D. Budens
Primary Examiner
Art Unit 1648

5 rdb
December 17, 2001